

FOLLOW UP AND OPTIMISATION OF CARDIAC PACING

Electrophysiology

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Pacemaker implantation is only the initial phase in the lifelong management of the patient with a pacemaker. The challenge of this treatment lies in the comprehensive follow up of the device. As the number of implanted devices increases so does the burden of follow up. This is compounded by increasing data provided by devices and increasing sophistication in programming therapy and detection algorithms. There are some general guidelines on pacemaker follow up provided by national organisations, but very little provided in the way of detail.^{1–3} This is reflected in the immense variation in the manner of pacemaker follow up both nationally and internationally. Like most medical interventions pacemaker follow up has to be tailored to the individual. The fundamental principles of pacemaker follow up are listed in table 1.

▶ PACEMAKER CLINIC RESOURCES

In order to follow up patients with implanted devices adequately there has to be a basic resource provision in terms of real estate, equipment, and appropriately trained personnel. A dedicated area for pacemaker follow up should be provided which enables the patient to have their appointment performed in privacy and safety. Full resuscitation facilities should be immediately available, though recourse to resuscitation facilities as a direct consequence of a pacemaker follow up is extremely rare. Relevant pacemaker programmers and appropriate technical information for all followed pacemakers should be available. A comprehensive list of basic required equipment is described in table 2. Pacemaker follow up is increasingly performed by non-medical staff such as cardiac physiologists (technicians) and nursing staff. The facility should exist in these circumstances for the patients to have access to medical input in the event of an emergency or problematic follow up. There should be a basic competency level of those staff performing follow up. This level is often defined at a national level but should certainly be defined locally.

PACEMAKER FOLLOW UP PROCEDURE

The frequency of pacemaker follow up varies from centre to centre. Follow up can be divided into three phases: early surveillance, maintenance period, and intensified monitoring period. In most cases a first follow up after discharge from hospital should be within four to six weeks (early surveillance). Thereafter follow up will be generally every six or 12 months (maintenance period). In the paediatric population this should be at least every six months. More intense follow up will be necessary as the device approaches the end of its battery life (for example, 75% of battery capacity consumed—intensified monitoring period). A history should be taken from all patients to identify whether there are likely to be any pacemaker related problems or clinical problems that may be aided by alternate device programming. Specifically, change in symptoms such as presyncope, syncope, dyspnoea, lethargy, palpitations, and chest pain should be defined. A full medication review should be considered as part of the follow up process.

The device should be interrogated using the appropriate programmer and software. Table 3 defines those parameters that should be evaluated and recorded and considered as minimum essential data for follow up. In the first instance analysis of endocardial electrograms will be performed followed by pacing lead integrity. In the majority of cases this will be in the form of a calculated impedance value. Providing this is satisfactory pacing and sensing parameters should be recorded. An important aspect of this will be comparison with previous recorded values and analysis of trends in order that potential problems may be predicted. Most devices record further information that can be invaluable in patient care. This may be in the form of rate histograms, recorded electrograms, activity levels, mode switches, etc. The next section will concentrate on the more advanced features of current pacemaker technology that need to be managed and optimised at the time of pacemaker follow up.

AUTOMATIC CAPTURE MEASUREMENT

Many devices have the ability to determine the pacing threshold and adjust the output of the device to just above this threshold. This compares to setting the output at a fixed level usually

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Table 1 Fundamental principles of pacemaker follow up

- ▶ Evaluation of correct device function and patient safety (to national standards)
- ▶ Optimisation of system function and maximisation of device longevity
- ▶ Aim to comprehensively troubleshoot pacemaker problems/complications
- ▶ Provision of patient/family support and education
- ▶ Appropriate storage of data
- ▶ Scheduling of next visit or device replacement

twice the threshold of the last pacing check. The first pacemaker to be successfully introduced with automatic capture was in 1995. Algorithms to check threshold usually require the delivery of a pacing pulse at decrementing outputs and the evaluation of a sensed evoked response following this pulse. If no evoked response is recorded a pacing pulse at a fixed high output is delivered to ensure capture. Often this testing is programmed to occur at night time so as to avoid symptoms. Key requirements to such a system are the determination of the evoked response and ability to distinguish from the polarisation signal (that is, pacing “spike”). Evoked response may take a period of weeks/months to stabilise in terms of consistency of amplitude and may vary with changes in the patients’ physiology and pharmacotherapy. A requirement of such a system is a bipolar lead. Generally, the evoked response in the atrium is of inadequate amplitude to make such a facility reliable for atrial pacing. Some devices examine the period following a test pulse looking not for an evoked response but for a sensed intrinsic atrial electrogram indicating failure to capture and thus intrinsic activity.

Capture management algorithms are currently well established in ventricular pacing and are beginning to evolve in atrial pacing. This automatic facility has potentially a number of benefits. By reducing the output there will be less drain on the battery and potentially increased device longevity. This has been demonstrated to increase device longevity by up to 65%.³ More importantly the device has the ability to adjust to alterations in threshold and thus has an important safety mechanism. It is possible for the threshold of the lead to increase for a number of reasons, including device related problems such as micro displacement, or changes in physiology such as electrolyte abnormalities, or alteration in pharmacology such as antiarrhythmic drugs. These changes will be very apparent when the threshold trend data are reviewed.

EVENT COUNTERS

Counter information provides data regarding the total number or percentage of paced and sensed events in both the atrium and the ventricles since the counters were reset. Counters are usually reset at the completion of the last pacemaker check. It will also indicate the number of atrial and ventricular extrasystoles, atrial/ventricular tachycardias, and will also indicate the number of times certain algorithms are activated—for example, mode switch, rate drop response, etc. With the knowledge of the patient’s underlying cardiac status and rhythm this information can be used to program the device optimally. It is important that the amount of pacing that a patient receives from their device is carefully evaluated each time. The general principal should be to

Table 2 Basic resources required for pacemaker follow up

- ▶ Technical information on devices and previous follow up data
- ▶ ECG monitor/12 lead recorder
- ▶ Appropriate pacemaker programmer
- ▶ Full resuscitation equipment
- ▶ Medical grade pacemaker magnets
- ▶ Access to database for data collection and retrieval
- ▶ Facilities to admit patients in the event of an emergency

encourage as much intrinsic activity as is possible and physiologically appropriate. This ensures more physiological cardiac performance, has less drain on the battery life, and may make the individual less pacing dependant. This has to be balanced with the patient’s degree of electrical conduction abnormality and potential chronotropic insufficiency. Encouraging intrinsic activity is usually possible by altering parameters such as the atrioventricular (AV) delay or lower rate limit. A number of algorithms have dynamic AV delays that aim to maximise intrinsic conduction.

ELECTROGRAM STORAGE

Most pacemakers have the ability to record electrograms along with annotated markers when predefined events occur. Marker annotation allows an understanding of device behaviour but can provide inaccurate information in a number of different circumstances such as over/undersensing, cross talk, interference and far-field sensing. The real value is in the analysis of the recorded endocardial electrograms.⁴ Experience of endocardial electrograms is extensive from implantable cardioverter-defibrillators (ICDs) that document therapy events. Stored electrograms have provided the clinician with an invaluable tool in aiding clinical follow up of arrhythmias and potential trouble shooting of device related programming issues or hardware problems such as lead fracture or displacement (fig 1).⁵ Most devices now will allow a number or pre-programmed events to be recorded, varying from a few seconds to several minutes. Each event may also include two sections: an onset recording, and post trigger period—that is, after detection criteria made. Recording the onset section greatly enhances arrhythmia diagnosis.⁶ Activating the facility to record electrograms reduces battery longevity by only a small amount—for example, two days in a year.

The recorded electrograms allow analysis of potentially non-symptomatic events, although the time of recording is made and subsequently can be correlated with symptom history. Myopotential interference is now less of a problem as many pacemaker systems have bipolar leads. However, some patients have unipolar leads that have been in place for many years and are functioning appropriately. Occasionally

Table 3 Essential minimum information to be recorded at the time of pacemaker follow up

- ▶ Pacing lead impedance
- ▶ Sensed P/R wave amplitude
- ▶ Pacing threshold
- ▶ Battery voltage and impedance

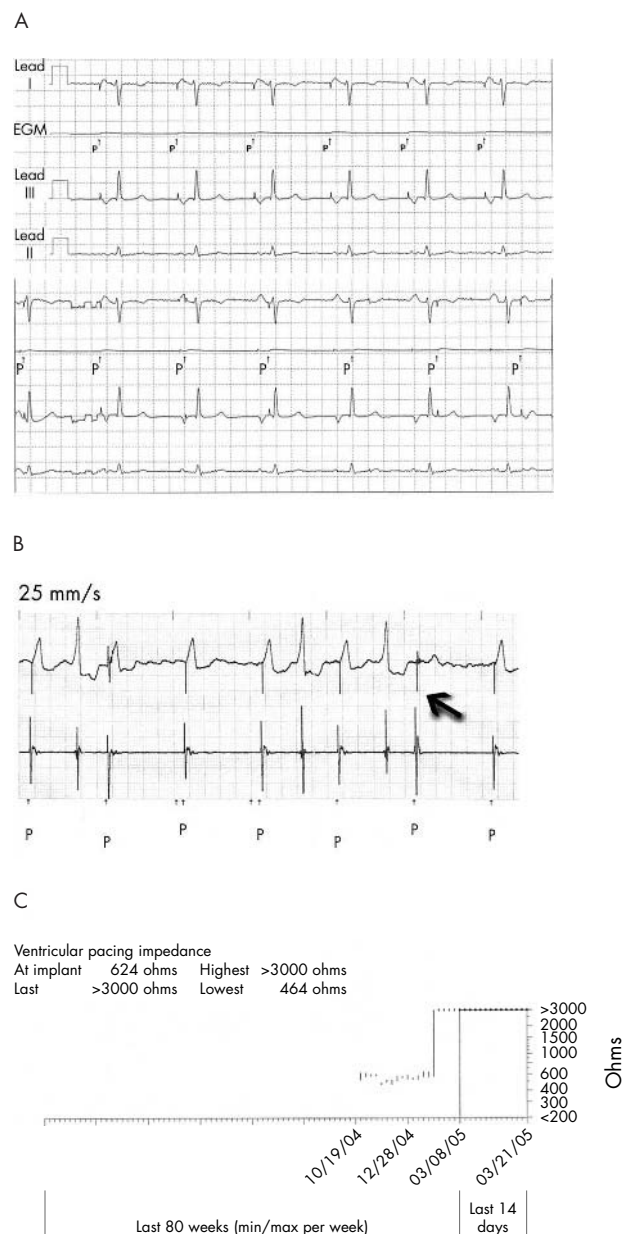


Figure 1 Pacemaker complications observed at follow up. (A) Microdisplacement of atrial lead in patient with sick sinus syndrome leading to intermittent failure to accurately atrial sense. This results in atrial pacing "spikes" wandering through the QRS complex. This patient required lead repositioning. (B) Incorrect ventricular sensitivity setting resulting in failure to sense intrinsic ventricular electrograms. This leads to failure of next impulse to capture (arrow) as falling within refractory period of previous complex. Adjustment of ventricular sensitivity corrected this problem. (C) Recurrence of patient's symptoms four months after pacemaker was implanted. Histogram demonstrates a sudden rise in ventricular lead impedance and a chest x ray confirmed subclavian lead crush.

insulation complications can warrant programming of leads from bipolar to unipolar. Inappropriate sensing of myopotential activity in these circumstances may lead to inhibition of pacing and potentially syncope. Having the ability to correlate counters with the electrograms makes the diagnosis of this issue relatively straightforward. Patient triggered diagnostics may be recorded by activating a device held by the patient or in the case of some devices activation using a

magnet. Stored electrograms at the time of symptoms will establish whether the cause is an arrhythmia or device related problem. This allows the device to be used and the clinical data applied in a similar manner to an implanted loop recorder.⁷ Additional asymptomatic stored electrograms may include prognostically significant ventricular arrhythmias or asymptomatic atrial arrhythmias that may indicate the need for formal anticoagulation. A limitation of stored electrograms is the compression of the data in order to record adequate electrogram sequences. This can produce less clear endocardial recordings in some cases.

RATE RESPONSE

Rate response (adaptive) pacing allows an increase in heart rate with level of physical activity.⁸ A number of activity sensors have been developed using different algorithms such as QT interval, minute ventilation, stroke volume, and accelerometers. Some devices have combined or so called blended sensors. The rate response is programmable with an upper limit and sensitivity. These parameters have the potential to significantly impact on an individual's performance and thus effort should be spent in tailoring the settings of rate response to an individual. Careful analysis of the counters should enable an assessment of the appropriateness of the current rate sensor settings. Factors to be considered should include the age of the patient, the relative activity of the individual, additional health issues, and pharmacological treatment. The increased use of β blockers in the management of heart disease can also account for an inadequate increase in heart rate with activity and thus should be taken into account when adjusting the device settings. An inadequate sensitivity or upper limit may produce symptoms of lethargy, dyspnoea, palpitations, or presyncope on exertion.

MODE SWITCHING AND ATRIAL ARRHYTHMIA ALGORITHMS/TREATMENTS

The ventricular rate of DDD pacemakers is dependant on the atrial rate. Therefore, there is the potential for very fast ventricular rates to be tracked by the pacemaker should the patient develop an atrial tachycardia. This is not an unusual occurrence in paced patients. A significant number of patients with sinus node disease have tachycardia-bradycardia syndrome and there is also an increasing incidence of atrial fibrillation with increasing age. It has been demonstrated that the incidence of atrial fibrillation in paced patients is as high as 13% with an overall risk of 2–3% per year developing atrial fibrillation.⁹ The most common reason (38%) for reprogramming a pacemaker at the time of follow up is for an arrhythmia and the most frequent programming change is the stimulation mode (81%).¹⁰ Fast tracking of atrial tachyarrhythmias is usually prevented by algorithms known as automatic mode switching (AMS).^{11–12} The detection of the atrial arrhythmia will depend on the algorithm but usually involves the detection of sudden onset of a fast atrial rate. This will then produce a change in the programmed mode switching from DDD to DDI, VDI or VVI mode. The device will revert back to dual chamber mode when sinus rhythm is restored. The number of mode switching events is recorded providing an accurate assessment of the number of episodes of atrial arrhythmias. This provides invaluable information that may allow the clinician to alter the patient's medical management or consider more interventional approaches such as catheter ablation. It also provides a

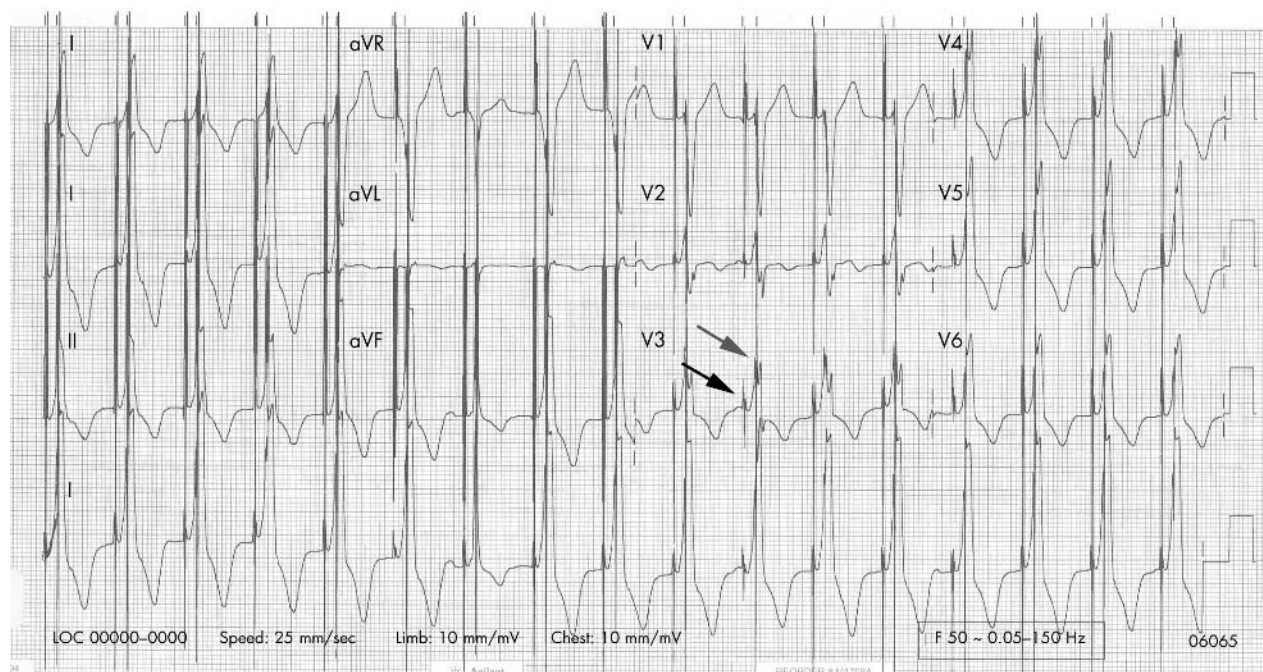


Figure 2 This ECG was recorded at a patient's first follow up visit following implantation. While the patient was asymptomatic the ECG demonstrates that the first pacing pulse (black arrow) stimulates the ventricle and the second pulse (grey arrow) falls within the QRS complex. A plain chest x ray confirmed that the atrial lead had displaced into the right ventricle.

mechanism for assessing the response to such an intervention. If the patient has retrograde conduction through the atrioventricular node then there exists the potential mechanism for a pacemaker mediated tachycardia (PMT) to develop with ventricular tracking of the retrograde atrial conduction. Most devices contain algorithms to prevent this and these should be considered if retrograde ventricular atrial conduction has been demonstrated.

A number of triggers of atrial arrhythmias and specifically atrial fibrillation have been demonstrated. These include atrial premature beats (APB), pauses after APBs, and increased vagal tone. Many currently available devices have algorithms that may be activated in order to reduce the number of episodes of atrial arrhythmias by suppressing APB activity or reducing the short-long sequence seen with an APB. Algorithms aim to dynamically overdrive pace the atrium by pacing at a rate just above the intrinsic rate or "smooth" the atrial rate by pacing after APBs, thus preventing short-long cycle lengths. In those patients who have vagally mediated atrial fibrillation the prevention of a sudden reduction in atrial rate can be eliminated by atrial pacing. Typically this may occur after vigorous physical exercise. The early recurrence of atrial fibrillation (ERAF) has also been addressed by some algorithms by high rate atrial pacing immediately after the termination of atrial arrhythmia.¹³ Some devices have the ability to treat atrial arrhythmias using anti-tachycardia pacing in a manner similar to ICD therapy for ventricular tachycardia.

BATTERY STATUS

Interrogation of the pacemaker will give an assessment of the current status of the battery. This information, combined with the patient's history—that is, per cent pacing—enables a prediction of the life expectancy of the device to be displayed.

Battery measurements are usually assessed several times each day. Battery status allows for planning of the next pacemaker follow up and ultimately pulse generator replacement. In most situations placing a magnet over the device will default to a fixed pacing mode at a rate determined by the battery status. For example, a fixed rate of 100/min may indicate satisfactory battery measurements with a reduction to 85/min for elective replacement time and < 85/min for end of life. These figures will vary from device to device but should be readily available at the time of pacemaker follow up.

TROUBLESHOOTING

At routine follow up it should be possible to identify any problems with the pacemaker system performance. System problems may relate to the hardware in terms of the pulse generator and leads or there may be a software issue in terms of device programming. An important aspect of pacemaker follow up is the management and systems employed to react to device alerts or recalls.

Pulse generator failures are extremely unusual but do occur. This may present in a number of manners ranging from complete system failure and inability to communicate with the device to premature battery depletion or malfunction of one or more components of the device. Lead related problems are more commonplace and should be identified at a pacemaker follow up visit (fig 2). Lead failure may occur for many reasons such as lead fracture, displacement, exit block, drug treatment, etc. Lead failure may be seen at pacemaker follow up by a change in sensed electrogram (size or interference), pacing threshold, or impedance.¹⁴ Most of these data are presented at follow up in trend graphs (fig 1C). If a lead related problem is suspected then radiological imaging will be required (fig 3). In the first instance this is

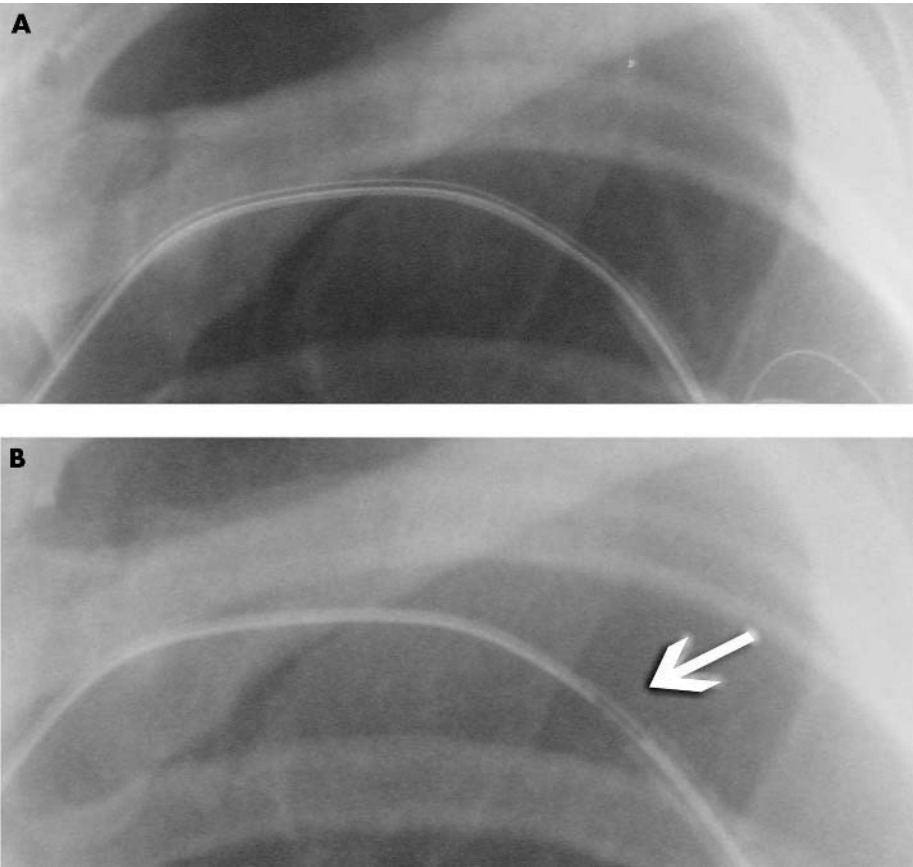


Figure 3 This patient reported recurrent syncope four months after a routine pulse generator change. A repeat chest film demonstrated a clear fracture (arrow) in the pacing lead compared to the film taken before the generator change (top). This required replacement of the ventricular lead.

likely to be a plain chest radiograph, but more careful assessment may be required with high intensity fluoroscopic screening.¹⁵ If a lead failure is suspected then facilities to admit the patient for further imaging or device revision should be available.

Occasionally patients will report deterioration in their symptoms or onset of new symptoms. It should be possible by appropriate use of the diagnostic information presented by the device to determine whether this is a pacemaker related issue or not. The psychological impact of pacemaker therapy should not be underestimated. The dependence on device therapy can have devastating consequences in some patients. It is important to be able to offer the appropriate support and counselling to patients in these circumstances.

ENVIRONMENTAL INTERACTIONS

The pacemaker industry has concentrated significant resources into the prevention of environmental interaction with pacemaker systems. However, increasing environmental sources of electromagnetic radiation makes this challenging. Electromagnetic interference has the potential to cause a pacemaker to respond in a number of ways: inappropriate inhibition or triggering of pacemaker output, asynchronous pacing, reprogramming to backup mode, or even irreversible damage to pacemaker components (table 4).¹⁶

DEVICE ADVISORIES AND RECALLS

There is a certain inevitability that as pacemaker technology progresses there will be some device failures. When these are

Table 4 Potential sources of electromagnetic interference of pacemaker systems

Environmental interaction	Potential interaction	Advice
Electronic antitheft surveillance devices Cellular telephones	Pacemaker inhibition, undersensing or oversensing Temporary asynchronous pacing or inhibition (only if device placed directly over generator)	Patient advised to move through devices quickly Use of contralateral ear to device or use “hands free” device
High voltage generators or arc welding	Inhibition of pacing	Work environment assessed to quantify any possible interference Avoid
Magnetic resonance imaging (MRI)	Inhibition or asynchronous pacing, irreversible device malfunction, or lead displacement	
Electrocautery devices and diathermy	Inhibition of pacing and irreversible device malfunction. Increased pacing threshold	Use of bipolar diathermy, programming of device to fixed rate pacing before surgery if surgical field in proximity to pulse generator. Full assessment of device postoperatively
Therapeutic irradiation	Problems very rare but theoretically could cause irreversible malfunction	Shielding of device if close to irradiation field
Diagnostic radiology Defibrillation	No interaction Potential irreversible device malfunction	Maintain defibrillation paddles as far from pulse generator as possible. Consider anteroposterior paddle positions

Pacemaker follow up: key points

- ▶ Should only be performed with appropriate infrastructure and trained staff
- ▶ Main aim should be to ensure appropriate safe device function tailored to the individual and to meet national standards
- ▶ Personnel performing follow up should have a comprehensive knowledge of the advanced features of individual devices
- ▶ Care pathways should be in place to manage pacemaker related problems and device advisories/recalls

identified advisories are issued by national regulatory authorities such as the Food and Drug Administration (FDA) in the USA and the Medicines and Healthcare Regulatory Agency (MHRA) in the UK. In the last decade advisories in the USA affected 500 000 pacemakers and ICDs. Every centre performing pacemaker follow up should have in place an established policy on dealing with device related advisories and a mechanism of disseminating information to the appropriate personnel. Usually recommendations are made by the pacemaker manufacturer. This may involve software/programming changes, increased follow up or in some cases device extraction/replacement. In most situations these decisions will be made on clinical grounds with a shared decision with the patient. The mechanism and pathway to making these decisions need to be defined. It is clear that different centres and physicians manage advisories in different ways.¹⁷ All centres should have in place local procedures to facilitate the timely reporting of adverse incidents involving pacemakers to the appropriate authority. In the UK this is done by means of an online reporting system to the MHRA which results in a rapid turn around and investigation of potential problems.

REMOTE DEVICE FOLLOW UP

The facility for transtelephonic monitoring (TTM) of pacemakers has been in place for many years. Its uptake has varied between healthcare systems. As the sophistication of pacemaker devices increases the mode of follow up will inevitably change. The vast amount of data that can now be retrieved from a pacemaker is likely to continue to increase and so the manner of follow up has to adapt. With wireless technology and transtelephonic/internet communication the need for a patient to come to the clinic or hospital and have a wand placed over their device is likely to become obsolete. It is likely that patients will have their devices interrogated each night by a unit in their home that communicates the interrogated information transtelephonically to a secure server where the data are available to the patient's physician. Most pacemaker manufacturers now have in place systems to allow remote pacemaker follow up. The real advantage of this system is the ability for more regular but less intrusive follow up and the potential to troubleshoot in a more expeditious manner. Programming of devices in a remote fashion carries a number of regulatory issues and concerns with safety and so it is likely that interrogation may only be possible remotely.

THE FUTURE OF PACEMAKER FOLLOW UP

There have been dramatic changes in pacemaker technology over a relatively small timescale. Pacemaker follow up has mirrored this in terms of its complexity and level of expertise required to keep up with these technological advances. It is

likely that the next phase in development of the technology might be in advances in physiological data obtained from devices. Increasingly ICD technology provides us with biomedical data such as heart rate variability, transthoracic impedance, etc. As sensors are developed to assess cardiac output and blood pressure it is likely that pacemaker follow up will involve more clinical interpretation of these types of data rather than the mostly technical data that are presented at the moment. In response to this there is a trend to increasing the automatic management of such technical aspects of device function. With remote data management strategies we are likely to see a more holistic and comprehensive approach to patient follow up.

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